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In re Application of:	Group Art Unit: 1645
A. SAID EL SHAMI	Examining Attorney: DEVI, SARVAMANGALA J N
Serial No.: 09/036,819	
Filed: 3/9/1998	Pasadena, California
For: METHOD FOR MEASURING FREE LIGANDS IN BIOLOGICAL FLUIDS, AND ASSAY KITS FOR MEASURING SAME	Date: September 5, 2003

APPEAL BRIEF

This Appeal Brief is submitted pursuant to 37 CFR 1.192. This is an appeal from the FINAL REJECTION dated June 18, 2002.

1. Real Party In Interest

The assignee, Diagnostic Products Corporation, is the real party in interest.

2. Related Appeals and Interferences

There are no related appeals or interferences presently pending. The parent of this application, Application Serial No. 06/784,857, was involved in Interference No. 103933. An earlier filed patent application in this chain of applications, Serial No. 07/303,712, was

heard and decided by the Board, Appeal No. 94-0035.

3. Status Of Claims

Claims 56 is pending and is appealed. All other claims have been canceled.

4. Status Of Amendments

An amendment after final rejection was filed on December 18, 2002. By Office communication dated January 2, 2003, the Examiner indicated that Amendment would be entered for appeal.

5. Summary Of Invention

The invention relates to a diagnostic assay for the determination of the amount of free testosterone in a biological fluid sample in which an antibody for free testosterone, radioiodinated 6-hydroxy-testosterone-19-carboxymethyl ether histamine and sulfobromophthalein as a blocking agent are used. In circulating blood, testosterone is present both in the free or uncombined state and in the bound state, that is, the testosterone is bound to various circulating proteins known as endogenous binders. The present invention is adapted for the measurement of the level of testosterone in a sample which is naturally in the "free" state. The ability of discriminate between free and bound testosterone is important for various diagnostic purposes.

6. Issues

The issues on appeal are as follows:

1. Whether claim 56 is properly rejected under 35 USC 103(a) as being unpatentable over the count of Interference No. 101933.

2. Whether the claim is properly rejected under 35 USC 112, 2nd paragraph as being "indefinite".

All other issues have been resolved, see Office Communication of January 2, 2003 at page 2.

The Appendix hereto contains a true copy of the claim on appeal.

7. Grouping Of Claims

Claims 56 is to be considered as a whole and as a single group.

8. Argument

1. The Rejection Over the Interference Count - Citing 35 USC 103(a)

Interference No. 103,933 did contain claims generic to the instant claim 56 in the sense that the practice of claim 56 arguably might infringe applicants claim 1, for example, involved in the Interference (had the claim issued). Applicants original claim 1 involved in the Interference was held to be unpatentable over prior art and the Interference was terminated for lack of common patentable subject. There was no award of priority to any party. Original claims 2-27 were held to be unpatentable over the issue.

The Examiner is correct that certain individual elements of the method of claim 56 are found in one or more of the original claims 1 to 27. However, none of claims 1 to 27 claimed a method utilizing the combination of elements forming the subject matter of claim 56, viz,

(1) testosterone

(2) radioiodinated-6-hydroxy testosterone 19 carboxymethyl ether histamine

(3) an antibody specific for free testosterone

(4) sulfobromophthalein blocking agent.

The method using the combination of (1), (2), (3) and (4) was

(1) not claimed by this applicant (or any other party) in any of the claims involved in the Interference or held to be subject to the outcome of the Interference

(2) was not rejected by the Board on prior art

(3) Applicant could not have moved to add such a method claim to the Interference because none of the other parties had basis for such a claim as a review of their patent applications make clear (and as to which the Examiner apparently agrees).

The combination presented in claim 56 is clearly

(1) a different invention, (emphasis added)

(2) novel, and

(3) unobvious over the prior art.

Consider the Specification at page 26 which discloses that in a testosterone assay using sulfobromophthalein as the blocking agent, this blocking agent is uniquely effective in inhibiting the binding of the analog tracer (iodinated 6-hydroxy-testosterone-19 carboxymethyl ether histamine, Specification, p. 25, first paragraph), to the endogenous binder (albumin) without displacing testosterone bound to albumin.

Note this is to be contrasted with the use of salicylate, 2, 4-dinitrophenol and ANS (8-anilino-1-napthalenesulphoic acid) which result in the displacement of testosterone bound to albumin and increase the apparent free testosterone as measured by the method, an inflated and unsatisfactory result. Thus, the combination of (1) (2) (3) and (4) gives a result not obtainable by the overly broad claims involved in the Interference. Claim 56 is patentable over the prior art and is "patentably distinct" from the claims involved in the Interference. Claim 56 should be allowed. As stated in *In re Zletz*, 893 F.2d 319, 13 U.S.P.Q.2d 1320, 1322-1323 (Fed. Cir. 1989):

> "A losing party to an interference is entitled to claim subject matter other than that of the interference count, provided the requirements of patentability are met, and subject to those constraints that flow from the adverse decision in the interference. *Frilette*, 436 F.2d at 499-500, 168 U.S.P.Q. at 370-371 [In re Frilette, 436 F.2d 496, 168 U.S.P.Q. 368 (CCPA 1991)."

The Examiner especially refers to claims 17, 18, 20 and 23 of Application Serial No. 06/784,857. These claims are not drawn to the combination of reagents recited in claim 56. The individual components do not suggest the combination which prevents, as noted above, the falsely elevated or increased free testosterone level as measured by the method.

Winter v. Fujita, 53 USPQ 2nd 1478 (BPAI 2000) states (at 1482 and 1484):

". . . after the interference any applicant is free to present any new claim and the examiner will determine whether the claim is patentable", citing PTO Rule 658(c) relating to estoppel, and In re Deckler 24 USPQ2d 1448 (Fed. Cir. 1992).

Deckler holds that a party losing an interference is not entitled to claims to the same invention as the count. In re Zietz, 13 USPQ2d at 1323, cited above, further states:

> ". . . [A] losing party to an interference, on showing that the invention now claimed is not 'substantially the same' as that of the lost count, [In re] Frilette, 436 F.2d at 500, 168 USPQ at 371, may employ the procedures of Rule 131 in order to antedate the filing date of the interfering application. The lost count of the interference is not prior art against a different invention, for '"prior art" in the sense of section 102(g) cannot be the basis of a section 102(a) rejection, the invention not being publicly "known or used"'. In re Taub, 348 F.2d 556, 562, 146 USPQ 384, 389 (CCPA 1965) (emphasis in original) . . ."

See also Chisum, Vol. 2, Section 5.03[3] pp. 5-199 to 5-213.

In the instant case, none of the interfering parties in their Specifications disclosed or suggested the subject matter of claim 56. Thus, no rejection based on any other party's disclosure bars the allowance of claim 56 to appellant - under 35 USC 102 (e)/103.

There is no interference estoppel under Rule 658(c). The subject matter of claim 56 is to a different invention since no other party disclosed the combination of claim 56 Appellant could not have moved in the interference to add the combination of claim 56 to the counts.

The Examiner's continued reliance on 35 USC 103(a) is erroneous since the interference count is not "prior art" against a different invention, Zietz, supra.

Interference No. 103933 was terminated based on a finding that the count was not patentable to any party, based on prior art.

Claim 56 is not subject to rejection on this prior art, as the Examiner appears to acknowledge.

The only possible relevance the prior interference has here is that a party, having successfully argued that the interference claims are not patentable because of prior art, cannot subsequently contend that those claims or colorable variants thereof are patentable

to him.

However, claim 56 is not a colorable variant of any claim, including appellant's interference claims 1 to 27. Appellant could not be barred from asserting the patentablility of claim 56 which differs markedly from any interference count. It makes no sense to contend that appellant should have tried to add claim 56 to the interference since no other party had any basis for the subject matter of claim 56 and claim 56 gives results specific to a testosterone assay which are not common to the other blocking agents in the claimed combination using the recited specific radioiodinated analog.

The rejection based on the Interference and 35 USC 103 is unjustified and should be reversed.

2. The Rejection Under 35 USC 112 Second Paragraph

This rejection has been overcome by the claim 56. The Office Action of January 2, 2003, maintains under 35 USC 112, 2nd paragraph, the "rejection made in paragraph 13(a)" - referring to the Office Action of September 17, 2002 at page 6, top paragraph which read:

> "13. Claim 55 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.
>
> (a) Claim 55 lacks proper antecedent basis for the recitation "displacing testosterone bound to said endogenous binders" (see lines 14 and 15 of the claim).

Since there is already a recitation in the earlier part of claim 55 of "another portion of testosterones bound to one or more endogenous binders" (see line 3), is the recitation "testosterone bound to said endogenous binders" in lines 14 and 15 of the claim different from the one recited in line 3 of the claim?"

The language objected to in the Office Action of September 17, 2002 does not appear in claim 56. Prior claim 55 did contain the above quoted language which might have been construed as redundant or repetitive, or even uncertain. The rejection should be reversed since claim 56 is not subject to any of the criticisms set forth in Paragraph 13a of the Office Action of September 17, 2002.

Conclusion

All of the rejections should be reversed.

Dated: 9-5-03

Respectfully submitted,

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I hereby certify that this document in triplicate is being deposited on September 5, 2003 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Laura Velarde
Date: September 5, 2003

APPENDIX

Claim 56. A method for determining the concentration of the free testosterone in a biological fluid, wherein said free testosterone is in equilibrium with testosterone bound to one or more endogenous binders in said fluid comprising the steps of (a) forming a mixture of a sample of said fluid with (1) a specific antibody for the free testosterone, and (2) a labeled analog of testosterone which is radioiodinated 6-hydroxy-testosterone-19-carboxymethyl ether histamine that binds to said antibody and has affinity for the endogenous binders lower than that of testosterone for said endogenous binders, (b) maintaining said mixture to permit said labeled analog to compete with the free testosterone for binding with the antibody, (c) measuring the amount of said labeled analog that has, or has not, become bound to the antibody, and (d) determining the concentration of the free testosterone from said measurement, wherein the improvement comprises including in the mixture an amount of a blocking agent which is sulfobromophthalein to inhibit the binding of said labeled analog to the endogenous binders without displacing testosterone bound to said endogenous binders.